

110TH CONGRESS
1ST SESSION

H. R. 806

To amend the Federal Food, Drug, and Cosmetic Act to prohibit the marketing of authorized generic drugs.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 5, 2007

Mrs. EMERSON (for herself, Mr. BERRY, Mr. WAMP, and Mr. MOORE of Kansas) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to prohibit the marketing of authorized generic drugs.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. PROHIBITION OF AUTHORIZED GENERICS.**

4 Section 505 of the Federal Food, Drug, and Cosmetic
5 Act (21 U.S.C. 355) is amended by adding at the end the
6 following:

7 “(o) PROHIBITION OF AUTHORIZED GENERIC
8 DRUGS.—

9 “(1) IN GENERAL.—Notwithstanding any other
10 provision of this Act, no holder of a new drug appli-

1 cation approved under subsection (c) shall manufac-
 2 ture, market, sell, or distribute an authorized ge-
 3 neric drug, direct or indirectly, or authorize any
 4 other person to manufacture, market, sell, or dis-
 5 tribute an authorized generic drug.

6 “(2) AUTHORIZED GENERIC DRUG.—For pur-
 7 poses of this subsection, the term ‘authorized generic
 8 drug’—

9 “(A) means any version of a listed drug
 10 (as such term is used in subsection (j)) that the
 11 holder of the new drug application approved
 12 under subsection (c) for that listed drug seeks
 13 to commence marketing, selling, or distributing,
 14 directly or indirectly, after receipt of a notice
 15 sent pursuant to subsection (j)(2)(B) with re-
 16 spect to that listed drug; and

17 “(B) does not include any drug to be mar-
 18 keted, sold, or distributed—

19 “(i) by an entity eligible for exclu-
 20 sivity with respect to such drug under sub-
 21 section (j)(5)(B)(iv); or

22 “(ii) after expiration or forfeiture of
 23 any exclusivity with respect to such drug
 24 under such subsection (j)(5)(B)(iv).”.

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